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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named

Inventor : John H. Lee et al.

Appln. No. : 09/392,243

Filed : September 9, 1999

Title : Processes For Making Protein Hydrolysates From
Animal Peptone And For Preserving Mucosa

Docket No. : LL11.12-0073

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Group Art Unit: 1651

Examiner: Francisco
Chandler Prats

APPELLANT'S BRIEF IN REPLY TO THE EXAMINER'S ANSWER

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Sir:

This is Appellant's Brief in Reply (subsequently referred to as the "Reply Brief") to the Examiner's Answer that was mailed on March 3, 2003 in the pending Appeal before the Board of Patent Appeals and Interferences regarding the Examiner's final rejection of claims 21-27 and 36-54 in the above-identified application. Appellant's Reply Brief, filed in accordance with 37 C.F.R. § 1.193(b), is predominantly directed to Examiner's points of argument provided in the Examiner's Answer.

In the Examiner's Answer, the Examiner merely noted that the Brief For Appellant filed on January 6, 2003 includes a statement that claims 21-27 and 36-54 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8). The Examiner, in the Examiner's Answer, is required to state whether the Examiner disagrees with any statement in the Brief For Appellant that certain claims do not stand or fall together. (MPEP; 8th Ed., First Rev., February, 2003; page 1200-18). In the Examiner's Answer, the Examiner did not state whether the Examiner disagrees with any statement in the Brief For Appellant that certain claims do not stand or fall together. Therefore, Applicant presumes the Examiner agrees with all statements in the Brief For Appellant about certain claims not standing or falling together.

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The Examiner's Answer reiterates the rejection, previously stated in the Final Office Action dated July 2, 2002, of claims 21-27 and 36-54 under 35 U.S.C.103(a) as allegedly being unpatentable over Van Gorp et. al. (U.S. Patent 5,607,840) in view of Balslev et. al. (U.S. Patent 4,438,100) and Oles (U.S. Patent 4,145,451). Appellant again asserts that the Van Gorp, Balslev, and Oles patents, either separately or collectively, do not teach, suggest, or make obvious the invention of the above-identified application, as defined in claims 21-27 and 36-54. See generally §§ II, III, and IV of the Brief For Appellant. There is no teaching or suggestion in the art which would lead one of skill in the art to combine the cited references in the manner suggested by the Examiner.

All of Appellants' arguments made in the Brief For Appellant remain valid and probative, despite any contentions of the Examiner to the contrary in the Examiner's Answer. The arguments in the Examiner's Answer add some new characterizations to the substantive argument the Examiner stated in the Final Office Action dated July 2, 2002. The general nature and organization of the Examiner's does not follow the organization of argument presented in the Brief For Appellant. Therefore, for simplicity sake, Appellant invites the Board to rely on the Brief For Appellant as a road map to addressing the various claim rejections. In this Reply Brief, the principle thrusts of the Examiner's new arguments are addressed in a manner that (1) supplements Appellant's detailed arguments presented in the Brief For Appellant and (2) relies on the organization of argument presented in the Brief For Appellant.

II. The Van Gorp Patent, In View of The Balslev Patent And The Oles Patent, Does Not Teach, Suggest Or Make Obvious The Invention Of The Present Application, As Defined In Claims 21-27.

A. The Examiner Impermissibly Relied On Hindsight Reconstruction When Alleging Claim 21 Is Obvious.

In regard to argument provided in § II. A. of the Brief For Appellant, the Examiner alleges:

Appellant argues initially that because the references are not directed to relevant art areas

Appellant is simply inaccurate in stating that the food and pharmaceutical arts are not relevant to the preservation of proteins prior to hydrolysis. . . .

Thus, appellant's argument, that the food and pharmaceutical arts are not relevant to the preservation of proteins prior to hydrolysis, entirely ignores the plain disclosure of the reference. . . .

(Bottom of page 5 through the bottom of page 6 of the Examiner's Answer).

Thus, the Examiner alleges in the Examiner's Answer that Appellant argues the Van Gorp, Balslev, and Oles patents constitute references that "are not directed to relevant art areas." This is a mischaracterization of Appellant's arguments in the Brief For Appellant. Instead, after admitting that the Van Gorp patent "discloses preservation of mucosa that is later converted to a protein hydrolysate," Appellant argues the lack of connection between the Balslev preserved products and the Van Gorp product as well as between the Oles preserved products and the Van Gorp product:

There is no connection between the Van Gorp patent, the Balslev patent, and the Oles patent except for the invention defined in claim 21. The Van Gorp patent discloses preservation of mucosa that is later converted to a protein hydrolysate. On the other hand, the Balslev patent discloses a pharmaceutical type product that is used as an artificial saliva, ophthalmic solutions and carriers for medicaments. (See last sentence of abstract). Still further, the Oles patent discloses food products that are preserved without use of artificial preservatives by the synergistic effect of (1) acetic acid or other organic acids in combination with (2) phosphoric acid. (Col. 2, lines 31-34). The Examiner's combination of details from these references must fail to avoid improper hindsight reconstruction.

One skilled in the art would not attempt to combine process details concerning the industrial preservation of pig guts, where proteins of the pig guts are later broken down with an enzyme by hydrolysis, with details about formation of a pharmaceutical product such as artificial saliva and with details about formation of a food stuff, such as mayonnaise and salad dressing. Instead, the Examiner picked and chose elements from entirely unrelated references in an attempt to remedy the deficiencies of the Van Gorp patent and find claim 21 obvious. The Examiner improperly used the features defined in claim 21 as a map to find and combine details when alleging the present

invention, as defined in claim 21, is obvious. Therefore, the Examiner's rejection of claim 21 as allegedly being obvious should be reversed.

(Pages 10-11 of the Brief For Appellant). Thus, Appellant does not, as the Examiner alleges, argue the Van Gorp, Balslev, and Oles patents constitute references that "are not directed to relevant art areas." Instead, Appellant merely argues the lack of motivation for inserting the preservative of the Balslev preserved products into the Van Gorp mucosa, as well as, the lack of motivation for inserting the preservative of the Oles preserved products into the Van Gorp mucosa. The Examiner's cited comments on page 6 of the Examiner's Answer from the Van Gorp patent do not diminish the strength of Appellant's argument cited above.

The Examiner improperly used the features defined in claim 21 as a map to find and combine details when alleging the present invention, as defined in claim 21, is obvious. Therefore, the Examiner's rejection of claim 21 as allegedly being obvious should be reversed.

III. The Van Gorp Patent In View Of The Balslev Patent Does Not Teach, Suggest Or Make Obvious The Invention of The Present Application As Defined In Claims 36-52.

A. The Examiner Impermissibly Relied On Hindsight Reconstruction When Alleging Claim 36 Is Obvious.

Appellant's comments provided above in regard to § II. A. of the Brief For Appellant and in regard to the Examiner's allegation in the Examiner's Answer that Appellant argues the Van Gorp, Balslev, and Oles patents constitute references that "are not directed to relevant art areas" are equally pertinent to Appellant's argument provided in § III. A. of the Brief For Appellant. As noted in the Brief for Appellant:

The Oles patent was cited for the alleged proposition that phosphoric acid is a well known preservative. Since neither independent claim 36 nor dependent claims 37-52 include phosphoric acid as an element, the Oles patent is not relevant to the non-obviousness analysis of claims 36-52. As such, the Oles patent will not be discussed in §III of this Brief.

(Page 19 of the Brief for Appellant). Therefore, in this argument of the Reply Brief concerning claims 36-52, the Oles patent is not discussed in § III. A. of the Brief For Appellant.

As noted above in regard to § II. A. of the Brief For Appellant, the Examiner, in regard to Appellant's argument in § III. A. of the Brief For Appellant, alleges that Appellant argues the Van Gorp and Balslev patents constitute references that "are not directed to relevant art areas." This is a mischaracterization of Appellant's arguments in the Brief For Appellant. Instead, after admitting that the Van Gorp patent "discloses preservation of mucosa that is later converted to a protein hydrolysate," Appellant argues the lack of connection between the Balslev preserved products and the Van Gorp product. (See bottom of page 19 through page 20 of the Brief for Appellant).

Thus, upon reviewing Appellant's argument appearing from the bottom of page 19 through page 20 of the Brief for Appellant, Appellant does not, as the Examiner alleges, argue the Van Gorp and Balslev patents constitute references that "are not directed to relevant art areas." Instead, Appellant merely argues the lack of motivation for inserting the preservative of the Balslev preserved products into the Van Gorp mucosa. The Examiner's cited comments on page 6 of the Examiner's Answer from the Van Gorp patent do not diminish the strength of Appellant's argument cited above.

The Examiner improperly used the features defined in claim 36 as a map to find and combine details when alleging the present invention, as defined in claim 36, is obvious. Therefore, the Examiner's rejection of claim 36 as allegedly being obvious should be reversed.

II. The Van Gorp Patent, In View of The Balslev Patent And The Oles Patent, Does Not Teach, Suggest Or Make Obvious The Invention Of The Present Application, As Defined In Claims 21-27.

B. There Is No Teaching Or Suggestion In The Prior Art Which Would Lead One Skilled In The Art To Combine The Cited References.

The Examiner alleges the Van Gorp patent discloses the preservation of the mucosa starting material using "well-known preservatives". (Page 4 of the Examiner's Answer). The relevance of the Van Gorp patent as a reference for preservation of mucosa that is later converted to a protein hydrolysate is not contested. (Page 10 of the Brief For Appellant). However, the

Examiner's repeated misrepresentation of passages from the Van Gorp patent (such as col.4, lines 17-34 and lines 45-50), in combination with mischaracterization about the Oles patent and the Balslev patent are contested.

The Examiner admits: "Van Gorp differs from the claims in that Van Gorp does not use the claimed peroxide or phosphoric acid as a preservative." (Page 4 of the Examiner's Answer). However, the Examiner follows with this unsupported, conclusory allegation:

That is, because the artisan of ordinary skill at the time of applicant's invention would have had a reasonable expectation from Oles and Balslev that phosphoric acid and/or peroxide **would have functioned equivalently to the preservative disclosed by Van Gorp.**

(Page 4 of the Examiner's Answer; emphasis added). There is no evidence in the prior art supporting the assertion of equivalent function by the Examiner.

To remedy this failure, in the Examiner's Answer, the Examiner relies on the following three preservatives: propionic acid, sorbic acid and benzoic acid as exemplary preservatives. (Middle of page 7 of the Examiner's Answer). All three of these compounds are **organic** acids with known uses as preservatives in food, as the Examiner contends. However, there is no demonstrated relationship between these three compounds to the two preservatives, hydrogen peroxide and phosphoric acid, that are defined in claims 21-27 of the above-identified application.

The possibility posited by the Examiner in the Examiner's Answer that the three named organic acids compounds have multiple applications and are therefore allegedly equivalent in application to each other is not germane to the alleged equivalence of the hydrogen peroxide of the Balslev patent to the different chemical preservatives of the Van Gorp patent and is likewise not germane to the alleged equivalence of the hydrogen peroxide/phosphoric acid combination of the Oles patent to the different chemical preservatives of the Van Gorp patent. Simply put, the possibility posited by the Examiner in the Examiner's Answer that the three named organic acids compounds have multiple applications and are therefore allegedly equivalent in application to each other is a red herring that is irrelevant to the alleged obviousness of substituting the hydrogen peroxide of the Balslev patent for the different chemical preservatives of the Van Gorp patent and is likewise irrelevant to the alleged obviousness of substituting the hydrogen peroxide/phosphoric

acid combination of the Oles patent to for the different chemical preservatives of the Van Gorp patent.

Incorporation of the preservatives disclosed in the Balslev patent or incorporation of the preservatives disclosed in the Oles patent into the process disclosed in the Van Gorp patent is improper. There is no teaching or suggestion in the cited references that would lead one skilled in the art to combine the references. In fact, the references actually teach away from the Examiner's suggested combination. The obviousness rejection of claim 21 based upon the Van Gorp patent in view of the Balslev patent and the Oles patent is improper and should be reversed.

Similar comments pertain to the Examiner's related attempt to force the hydrogen peroxide of the Balslev patent or the hydrogen peroxide/phosphoric acid combination of the Oles patent in place of the different chemical preservatives of the Van Gorp patent in an attempt to match the language of claims 36-52. One again, however, there is no demonstrated relationship between these three compounds to the preservatives, peroxide-containing compound, hydrogen peroxide and phosphoric acid, that are defined in claims 36-52 of the above-identified application. Instead, as stated above, the possibility posited by the Examiner in the Examiner's Answer that the three named organic acids compounds have multiple applications and are therefore allegedly equivalent in application to each other is a red herring that is irrelevant to the alleged obviousness of substituting the hydrogen peroxide of the Balslev patent for the different chemical preservatives of the Van Gorp patent and is likewise irrelevant to the alleged obviousness of substituting the hydrogen peroxide/phosphoric acid combination of the Oles patent to for the different chemical preservatives of the Van Gorp patent.

Incorporation of the preservatives disclosed in the Balslev patent into the process disclosed in the Van Gorp patent is improper. There is no teaching or suggestion in the cited references that would lead one skilled in the art to combine the references. In fact, the references actually teach away from the Examiner's suggested combination. The obviousness rejection of claim 36 based upon the Van Gorp patent in view of the Balslev patent is improper and should be reversed. The arguments presented above in this § III. B are equally applicable to claims 23 and 25 that each specify a peroxide-containing compound, namely hydrogen peroxide. Therefore, the obviousness

rejection of claims 23 and 25 based upon the Van Gorp patent in view of the Balslev patent is also improper and should be reversed.

III. The Van Gorp Patent In View Of The Balslev Patent Does Not Teach, Suggest Or Make Obvious The Invention of The Present Application As Defined In Claims 36-52.

D. Claims 48 and 50 Define Details About Contacting The Hydrolyzed Mucosa Product With A Protein-Containing Material That Is Not Disclosed In The Prior Art.

The Examiner's comments on page 13 of the Examiner's Answer demonstrate the Examiner's failure to understand the meaning of the subject matter that is defined in claims 48 and 50 of the above-identified application.. The present application teaches that upon proteolytic enzymatic hydrolysis of mucosa into protein hydrolysate, some residual enzymatic activity may remain in the protein hydrolysate (e.g. hydrolyzed mucosa product). Claims 48 and 50 are directed to use of the residual enzymatic activity in the hydrolyzed mucosa product to hydrolyze additional "protein-containing material[s]" (e.g. raw materials, mucosa) and reduce the residual enzymatic activity of the hydrolyzed mucosa. Further discussion is found in § II. D., at pages 28-30, of the Brief For Appellant. Contrary to the Examiner's suggestion, the purpose of using the residual enzymatic activity of the hydrolyzed mucosa is not to hydrolyze enzymes, as the Examiner suggests. Instead, the purpose of using the residual enzymatic activity of the hydrolyzed mucosa is to fully harness the residual enzymatic activity of the hydrolyzed mucosa in the course of hydrolyzing additional "protein-containing materials."

Claims 48 and 50 are each believed allowable. Therefore, Applicants respectfully request that the Board consider and reverse the Examiner's rejection of claims 48 and 50 under 35 U.S.C. §103 based upon the Van Gorp, Balslev, and Oles patents and that claims 48 and 50 be allowed.

II. Claim 42 Is In Allowable Form And Is Definite.

In the Examiner's Answer the Examiner continues to allege that claim 42 is "indefinite for failing to particularly point out and distinctly claim the subject matter that applicant regards as the invention." In support of this rejection, in the Examiner's Answer, the Examiner states:

Claim 42 is confusing, and therefore indefinite. It is confusing what claim 42 recites because the claim initially recites addition of a peroxide-containing compound to a composition, but then recites that the added product must become undetectable when the amount of added product is measured. It is therefore unclear how much peroxide-containing product can be added, if any.

(Page 3 of the Examiner's Answer). Despite the Examiner's comments, claim 42 is believed to be definite within the meaning of the second paragraph of 35 U.S.C. §112.

The MPEP states that the definiteness requirement must be analyzed, not in a vacuum, but in light of: the application content; the teachings of the prior art; and the claim interpretation given by one of ordinary skill in the art at the time the invention was made. (MPEP, 8th Ed., Rev.1, February, 2003; pages 2100-199). Claim 42 reads as follows:

The method of claim 36, the method further comprising mixing the peroxide-containing compound and the mucosa tissue to form a mucosa product, the concentration of the peroxide-containing compound remaining in the mucosa product being undetectable when the concentration of the peroxide-containing compound remaining in the mucosa product is determined using KMnO_4 titration.

Support for the language of claim 42 exists in the specification of the above-identified application at page 4, lines 19-23; page 5, lines 19-25; and page 9, lines 23-25.

The Examiner's confusion regarding claim 42 is apparently caused by the Examiner's inability to grasp that claim 42 defines addition of an amount of peroxide-containing compound that reacts with the muscosa tissue, when practicing the invention in accordance with claim 42, where the reaction reduces the concentration of the peroxide-containing compound remaining in the mucosa product below the detection limit of the KMnO_4 titration procedure. One skilled in the art would understand from the language of claim 42 that the hydrogen peroxide is not detectable because a chemical reaction occurs between the mucosa tissue and the hydrogen peroxide immediately upon addition of the hydrogen peroxide that promptly reduces the concentration of the peroxide-containing

compound remaining in the mucosa product. The Examiner's failure to understand the highly reactive nature of peroxide-containing compounds, such as hydrogen peroxide, should not also be attributed to those of ordinary skill in the art, absent probative evidence to the contrary.

There is no evidence of record, or reason to believe, that one of ordinary skill in the art would be incapable of understanding the meaning and requirements of claim 42. Consequently, claim 42 is believed definite in accordance with the second paragraph of 35 U.S.C. §112. Therefore, Applicants respectfully request that the Examiner's rejection of claim 42 under the second paragraph of 35 U.S.C. §112 be reversed and that claim 42 be allowed.

III. Conclusion.

For the foregoing reasons and reasons set for in the Brief for Appellant, claims 21-27 and 36-54 are believed allowable. Reconsideration and reversal of the rejections of claims 21-27 and 36-54, along with allowance of claims 21-27 and 36-54 are respectfully requested.

Respectfully submitted,

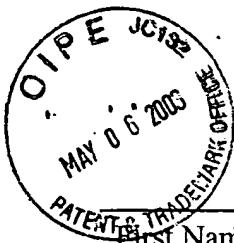
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The following papers are being transmitted via **EXPRESS MAIL** to the U.S. Patent and Trademark Office on the date shown below:

1. Appellant's Brief in Reply to the Examiner's Answer (10 Pages) (Three Copies - Total of 30 pages).
2. Return Receipt Postcard

Respectfully submitted,
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